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Patent and Trademark Office

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NOTICE OF ALLOWANCE AND ISSUE FEE DUE

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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
08/484,537	06/07/95	030	BURKE, J	1642 05/08/00
First Named Applicant	QUEEN, 35 USC 154(b) term ext. - 0 Days.			
TITLE OF INVENTION HUMANIZED IMMUNOGLOBULINS AND METHODS OF MAKING THE SAME				

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	11823-002630	435-069,600	M11 UTILITY	NO	\$1210.00	08/08/00

**THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.**

**THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.**

**HOW TO RESPOND TO THIS NOTICE:**

I. Review the SMALL ENTITY status shown above.  
If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number.  
Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

**IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.**

PATENT AND TRADEMARK OFFICE COPY

# Notice of Allowability

Application No.

08/484,537

Applicant(s)

Queen et al

Examiner

Julie E. Burke (Reeves), Ph.D.

Group Art Unit

1642



All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course.

☒ This communication is responsive to Sub Spec papers filed 1/18/00; 129(a) 2/17/00 and IDS filed 4/27/00.

☒ The allowed claim(s) is/are original 111-126, 131-144, renumbered as claims 1-30, respectively.

☐ The drawings filed on \_\_\_\_\_ are acceptable.

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

A SHORTENED STATUTORY PERIOD FOR RESPONSE to comply with the requirements noted below is set to EXPIRE **THREE MONTHS** FROM THE "DATE MAILED" of this Office action. Failure to timely comply will result in ABANDONMENT of this application. Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION, PTO-152, which discloses that the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.

☒ Applicant MUST submit NEW FORMAL DRAWINGS

☐ because the originally filed drawings were declared by applicant to be informal.

☒ including changes required by the Notice of Draftsperson's Patent Drawing Review, PTO-948, attached hereto or to Paper No. 8.

☐ including changes required by the proposed drawing correction filed on \_\_\_\_\_, which has been approved by the examiner.

☐ including changes required by the attached Examiner's Amendment/Comment.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the reverse side of the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any response to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

## Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s) 5, 6, 10, 19, 23, 41

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

☒ Interview Summary, PTO-413

☒ Examiner's Amendment/Comment

☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material

☒ Examiner's Statement of Reasons for Allowance

*J. Burke*

Serial Number: 08/484,537

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Paper # ~~111~~ 43  
Amat 1  
Page 2  
5/5/00

***Transitional After Final Practice***

1. Since this application is eligible for the transitional procedure of 37 CFR 1.129(a), and the fee set forth in 37 CFR 1.17(r) has been timely paid, the finality of the previous Office action is hereby withdrawn pursuant to 37 CFR 1.129(a). Applicant's first submission after final filed on 2/17/00 has been entered.

***Examiner's Amendment***

2. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment to correct the dependency of the claims was given in a telephone interview with Bill Smith on 5/5/00.

3. The application has been amended as follows: ✓

4. In originally filed claim 126, the phrase "~~or 126~~" has been deleted in order to correct the claim dependency. ✓  
"or 123"

5. The specification has been amended to correct formal matters as follows:

In the specification:

✓  
On page 1 line 5, the phrase --in part-- has been added after "continuation".

✓  
On page 1, line 8, the phrase -continuation is part-- has been added after "(now abandoned) and".

9.3  
5/5/00

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6. The following is an examiner's statement of reasons for allowance:

***Oath/Declaration***

7. The oath or declaration filed 12/23/99 has been entered.

8. The Amendment H, Terminal Disclaimers, Declaration, substitute specification, petition filed 12/23/99 have been entered. The red marked up copy of the substitute specification and statements that the substitute specification contain no new matter filed 1/18/00 have been entered.

9. Claims 111 and 143 had been amended by Amendment H filed 12/23/99.

10. A review of the substitute specification filed 12/23/99 and application 07/634,278, which issued as US Patent 5,530,101, found that the following text is newly added in the instant application and not present in the parent patent. For convenience, the column and line numbers of the patent are recited here. Pages 28, line 19 through page 29, line 35 of the Substitute specification are apparently added and these paragraphs are not present in corresponding text (see col 22, line 54) of US Patent no 5,530,101 This newly added text describes the variable regions of the heavy and light chains which form the antigen binding site and referred to hypervariable regions or CDRs as defined by either of Kabat or Chothia, as incorporated by reference. These definitions are substantive in this application in view of the file history and amendments of the claims. Accordingly, the first paragraph of the Substitute specification has been amended by the Examiner to recites that the instant application is a continuation in part of 07/634,278, in view of

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the additional, substantive material present in the Substitute specification which is absent from parent US Patent No 5,530,101.

11. The response set forth on page 1-3 of the response to advisory action and request for reconsideration under 37 CFR 1.129(a) filed 2/17/00 as Paper no 41 has been considered carefully but is deemed not to be persuasive. The response argues that the instant application is not a continuation in part of the parent application 07/634,278 and that this application is not a divisional of 07/634,278. This argument is not persuasive because in view of the material which will be printed when the instant application becomes a US Patent, which is not present in the US Patent '101 which issued from parent application '278, this application is a continuation in part.

***Claim Rejections withdrawn - 35 U.S.C. § 112***

12. The rejection of Claims 111-112, 115, 116, 139-142 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for humanization procedures, does not reasonably provide enablement for humanization that results in a selected variable region framework which is at least 65% or 70% identical to the donor immunoglobulin variable region framework is withdrawn in view of the statements provided 12/23/99, taken in view of the Declaration of Dr. Queen filed 12/23/99 as Paper no 23.

***Double Patenting rejection overcome***

13. The rejection of Claims 111-112, 115-116, 139-144 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over independent claims 1 and 35 of U. S. Patent No 5,693,761 or independent claim 1 of US Patent No 5,530,101 or independent

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claims 1, 11, 14 and 16 of US Patent No 5,693,762 is withdrawn in view of the Terminal Disclaimers filed 12/23/99.

14. The rejection of Claims 112 and 113 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,693,761, claim 3 of US patent 5,530,101 and claims 3 and 7 of US patent No 5,693,762 is withdrawn in view of the Terminal Disclaimers filed 12/23/99.

15. The rejection of Claims 113-114, 117-123, 124-126, 131-138 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 10, 11 and 37 of U.S. Patent No. 5,693,761 and claims 1-4 of US patent is withdrawn in view of the Terminal Disclaimers filed 12/23/99.

16. The rejection of Claims 111-113, 115-116, 139-144 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention withdrawn in view of the arguments set forth in the response filed 12/23/99.

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17. The rejection of Claims 111 and 143 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in view of the amendment(s) to the claims.

18. Claims 111-126 and 131-144 are now in condition for allowance.

***Information Disclosure Statement***

19. The following has been noted about the Opposition to EP 0456216 references cited on the Information Disclosure Statement PTO 1449 filed 4/28/00 as Paper no 42:

The references, papers, exhibits and attachments filed 4/28/00 have been considered by the Examiner.

References labeled as BD thru BP appear to have been misidentified on the PTO 1449 form, as BE thru BQ. The Examiner has corrected this apparent error on the PTO 1449 form. Accordingly, references BE thru BQ are now labeled as references BD thru BP on the PTO 1449, respectively.

20. The Opposition papers contain, as exhibits, many publicly available references, such as Exhibit B of reference AN; Exhibit 2 of AT; Exhibit 3 of reference BA, etc. The Examiner has considered all of the references, exhibits, attachments filed with the Information Disclosure Statement submitted 4/28/00 as Paper no 42. However, if applicants wish to have the citations of these readily publicly available references, including journal articles, to be printed individually on the face of the patent, it is suggested that Applicant file a PTO 1449 citing these references specifically. It is noted that any Information Disclosure Statement filed after the Notice of

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Allowance is sent out needs to comply with 37 CFR 1.97(e). Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609 ¶ C(1).

The origin and significant of the handwritten marks found on certain pages of the documents (page 19 of AH; page 1 of AT; page 1 of BA; page 1 of BE, for examples) is unclear, so the Examiner is unable to attribute any weight to such markings.

It is not clear how the papers filed with reference 28, section 2, "Observations of the Patentee", for example, relate to Opposition 0456216, as stated on the PTO 1449 form, because Section 2 is cited with regards to Oppositions Against European Patent No 0451216. Additionally, page 1 of reference AD, for example, refers to European Patent No 0451,216 and not to EP 0456216, as listed on the PTO 1449 form. It is noted the Opposition number on the front of the references differs from that on the PTO 1449 form. Because it is not readily apparent to the Examiner which of the numbers are correct, no changes have been made to the PTO 1449 form to correct the possible identification discrepancy.

The various references mention specific claim numbers which appear to be or to have been under review in a separate proceeding in Europe. The specification, priority documents, and claims currently under review in the European Opposition are apparently not present in the references filed 4/28/00 for the Examiner to consider. Nor is the Examiner provided with a



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comparison of the claims currently under review in Europe to those pending in the instant application. Nor is the Examiner provided with a comparison of the statutes, treaties and rules which apply to European Opposition proceedings to those statutes and rules used for determining patentability of claims in the United States. Therefore, although the examiner has considered all the references filed 4/28/00, this consideration is limited to a comparison of the various statements to the evidence of record in this case. It is not within the purview of this Office to determine matters of patentability of claims which are under review in European Oppositions.

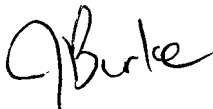
The statements made by various individuals (for example, documents AA and AG, which are written by an individual who apparently, coincidentally shares the same first and last names as those of a fictitious cartoon character) have been reviewed, but absent evidence of such individual's qualifications in this field, these documents are considered to be that of opinion only. None of the various declarations or references or papers filed in the European Opposition papers comply with the rules the USPTO relies upon for the evaluation of 37 CFR 1.131 declarations or 37 CFR 1.132 declarations. Thus these documents have not been considered by the Examiner as such or given the weight that proper declarations submitted under 37 CFR 1.131 or 1.132 are accorded.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue

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fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julie E. Burke, nee Reeves, Ph.D. whose telephone number is (703) 308-7553.



Julie E. Burke, nee Reeves, Ph.D.

May 5, 2000

JULIE BURKE  
PRIMARY EXAMINER